

U.S. Application No.: 10/048,123

Group Art Unit No.: 1625

**Amendment to the Claims:**

This listing of claims will replace all prior versions and listing of claims in the application:

Claims 1-14.(Cancelled).

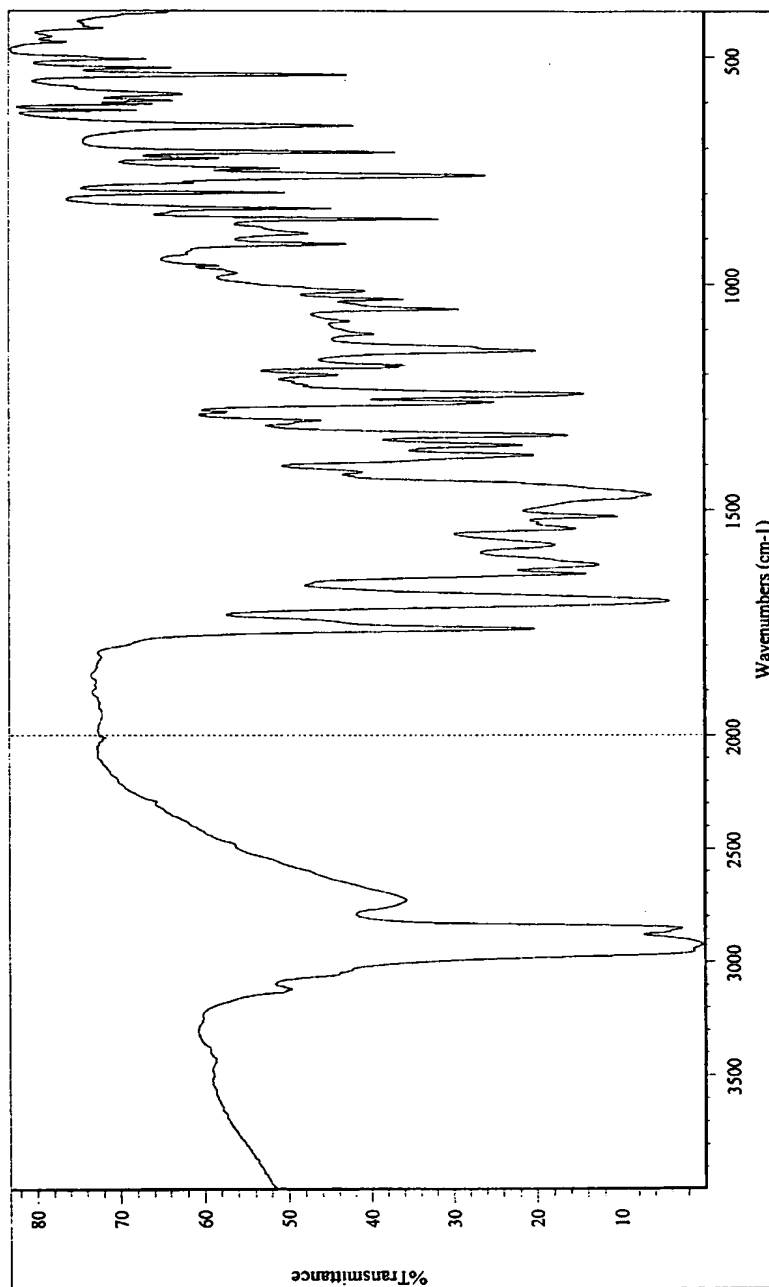
Claim 15 (Previously presented): A compound which is a polymorphic form of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, maleic acid salt, wherein said compound provides at least one of:

- (i) an infra red spectrum containing peaks at 1763, 912, 856 and 709  $\text{cm}^{-1}$ ;
- (ii) a Raman spectrum containing peaks at 1762, 1284, 912 and 888  $\text{cm}^{-1}$ ;
- (iii) a solid-state  $^{13}\text{C}$  nuclear magnetic resonance spectrum containing peaks at 111.0, 113.6, 119.8, 129.1, 130.9, 131.8, 134.7, 138.7, 146.5, 152.7, 157.5, 169.5, 171.0, 178.7 ppm; and
- (iv) an X-ray powder diffraction pattern having calculated lattice spacings at 5.87, 5.30, 4.69, 4.09, 3.88, 3.61, 3.53 and 3.46 Angstroms.



Claim 16 (Currently Amended): A compound according to claim 15, which provides which is a polymorphic form of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, maleic acid salt, wherein said compound, in a mineral oil dispersion, provides an infra red spectrum substantially in accordance with Figure I:

Figure I

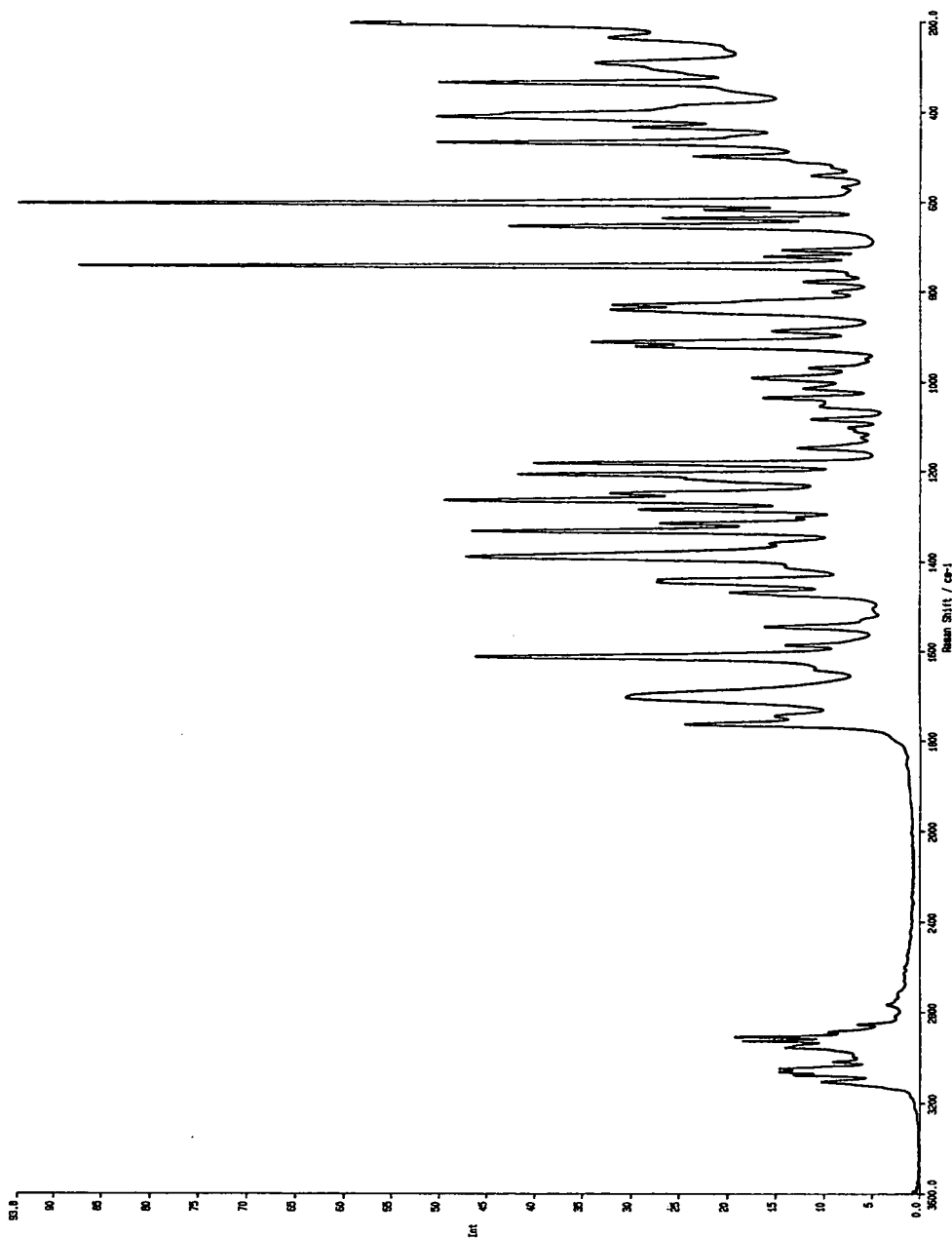


U.S. Application No.: 10/048,123  
Group Art Unit No.: 1625



Claim 17 (Currently Amended): A compound according to claim 15, which provides which is a polymorphic form of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, maleic acid salt, wherein said compound provides a Raman spectrum substantially in accordance with Figure II:

Figure II

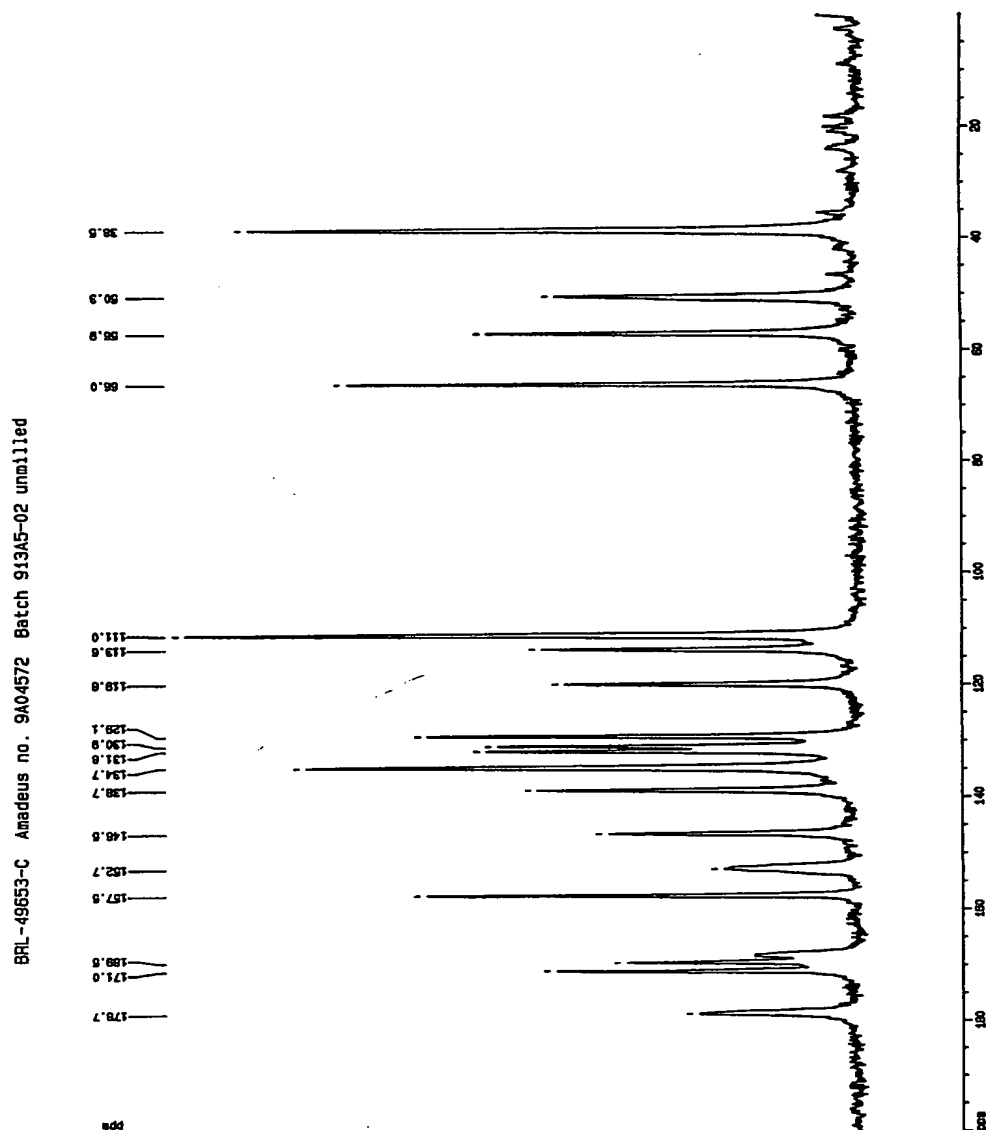


U.S. Application No.: 10/048,123  
Group Art Unit No.: 1625



Claim 18 (Currently Amended): A compound according to claim 15, which provides which is a polymorphic form of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, maleic acid salt, wherein said compound provides a solid-state  $^{13}\text{C}$  nuclear magnetic resonance spectrum substantially in accordance with Figure III:

Figure III



U.S. Application No.: 10/048,123

Group Art Unit No.: 1625

Claim 19 (Currently Amended): A compound according to claim 15, which provides which is a polymorphic form of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, maleic acid salt, wherein said compound provides a solid-state  $^{13}\text{C}$  nuclear magnetic resonance spectrum substantially in accordance with Table I:

Table I

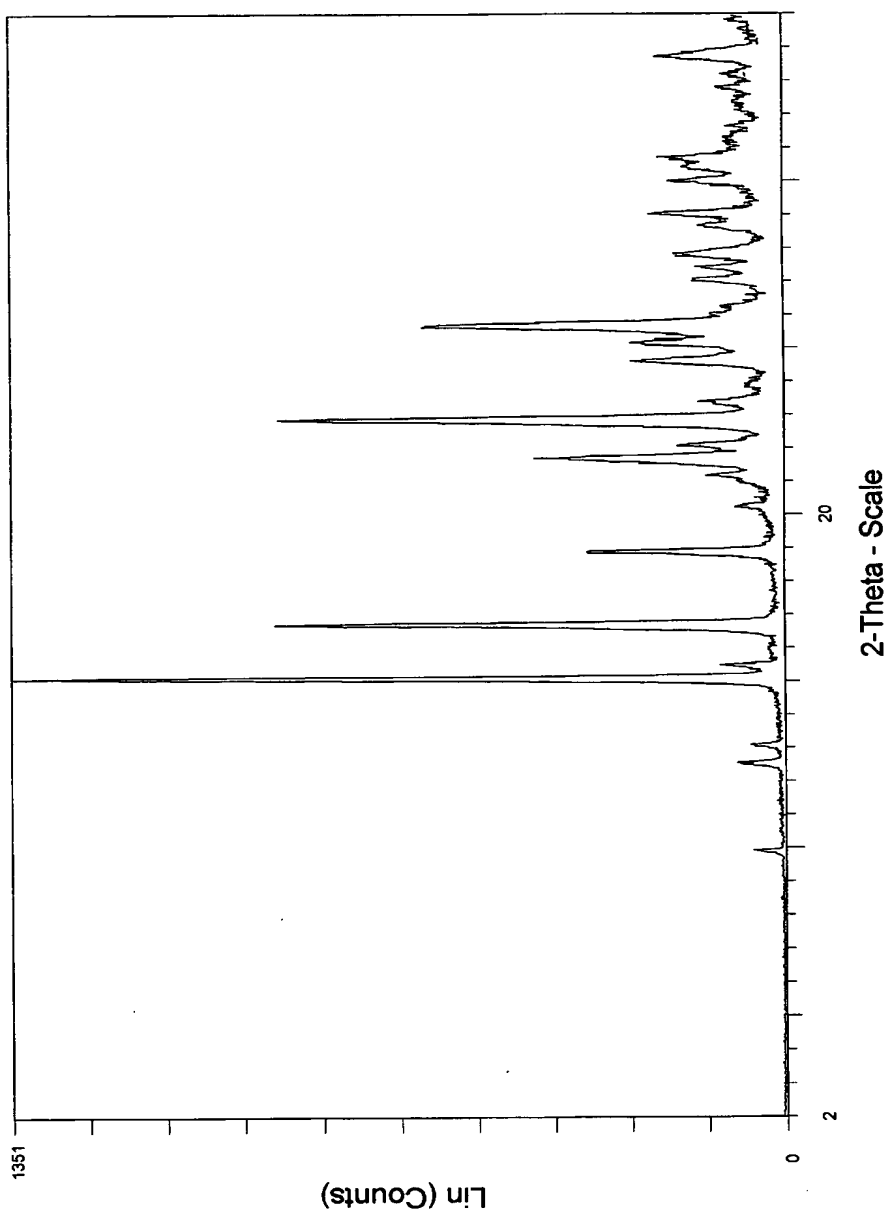
Chemical Shift (ppm)				
38.5	111.0	130.9	146.5	171.0
50.3	113.6	131.8	152.7	178.7
56.9	119.8	134.7	157.5	
66.0	129.1	138.7	169.5	

---



Claim 20 (Currently Amended): A compound according to claim 15, which provides which is a polymorphic form of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, maleic acid salt, wherein said compound provides an X-ray powder diffraction pattern substantially in accordance with Figure IV;

Figure IV



U.S. Application No.: 10/048,123

Group Art Unit No.: 1625

Claim 21 (Currently Amended): A compound according to claim 15, which provides which is a polymorphic form of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, maleic acid salt, wherein said compound provides an X-ray powder diffraction pattern substantially in accordance with Table II:

Table II

Diffraction Angle (°2θ)	Lattice Spacing (Angstroms)
9.9	8.97
12.5	7.07
13.1	6.78
15.1	5.87
15.5	5.72
16.7	5.30
18.9	4.69
20.3	4.38
21.2	4.19
21.7	4.09
22.1	4.02
22.9	3.88
23.4	3.80
23.9	3.72
24.6	3.61
25.2	3.53
25.7	3.46
26.3	3.39
27.1	3.29
27.5	3.25
27.9	3.20
28.7	3.11
29.1	3.07
30.1	2.97
30.5	2.93
30.8	2.91
31.3	2.85
31.7	2.82
32.9	2.72
33.2	2.69
33.8	2.65
34.0	2.64

U.S. Application No.: 10/048,123  
Group Art Unit No.: 1625

Claim 22 (Currently Amended): A compound according to ~~claim 15~~ any one of claims 15-21 in isolated form.

Claims 23 and 24 (Cancelled).

Claim 25 (Previously presented): A process for preparing the compound according to claim 15, comprising:

suspending 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, maleic acid salt in acetone; stirring the suspension at an elevated temperature for an extended period of time; and recovering the compound.

Claim 26 (Currently Amended): A process for preparing the compound according to claim 15 any one of claims 15-21, comprising:

seeding a solution of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, maleic acid salt in denatured ethanol at an elevated temperature with crystals of the compound; cooling the seeded solution; and recovering the compound from the denatured ethanol.

Claim 27 (Currently Amended): A pharmaceutical composition comprising an effective, non-toxic amount of the compound according to ~~claim 15~~ any one of claims 15-21 and a pharmaceutically acceptable carrier therefor.

Claim 28 (Currently Amended): A method for the treatment or prophylaxis of diabetes mellitus, conditions associated with diabetes mellitus and certain complications thereof, in a human or non-human mammal which comprises administering an effective, non-toxic, amount of the compound according to ~~claim 15~~ any one of claims 15-21 to a human or non-human mammal in need thereof.

Claim 29 (Currently Amended): A method for the treatment of Type II diabetes in a human comprising administering an effective, non-toxic amount of the compound according to ~~claim 15~~ any one of claims 15-21 to a human in need thereof.



U.S. Application No.: 10/048,123

Group Art Unit No.: 1625

Claim 30 (Original): A method of claim 29, wherein the administering comprises oral administration.

Claim 31 (Previously presented): A method of claim 30, wherein the compound is administered in the form of a tablet or capsule for said oral administration.

Claim 32 (Original): A composition according to claim 27 which is adapted for oral administration.

Claim 33 (Original): A composition according to claim 32 which is in the form of a tablet or a capsule for said oral administration.

Claim 34 (Previously presented): A compound which is a polymorphic form of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, maleic acid salt, wherein said compound provides:

- (i) an infra red spectrum containing peaks at 1763, 912, 856 and 709  $\text{cm}^{-1}$ ;
- (ii) a Raman spectrum containing peaks at 1762, 1284, 912 and 888  $\text{cm}^{-1}$ ;
- (iii) a solid-state  $^{13}\text{C}$  nuclear magnetic resonance spectrum containing peaks at 111.0, 113.6, 119.8, 129.1, 130.9, 131.8, 134.7, 138.7, 146.5, 152.7, 157.5, 169.5, 171.0, 178.7 ppm; and
- (iv) an X-ray powder diffraction pattern having calculated lattice spacings at 5.87, 5.30, 4.69, 4.09, 3.88, 3.61, 3.53 and 3.46 Angstroms.

Claim 35 (Currently Amended): A pharmaceutical composition consisting essentially of an effective, non-toxic amount of the compound according to ~~claim 15~~ any one of claims 15-21 and a pharmaceutically acceptable carrier therefor.

Claims 36-41 (Cancelled).

Claim 42 (New): A method for the preparation of a pharmaceutical composition comprising admixing an effective, non-toxic amount of the compound according to any one of claims 15-21 with a pharmaceutically acceptable carrier therefor.